Remarks

Courtesies extended to Applicants' representatives during the personal interview held on November 12, 2008, are acknowledged with appreciation. The contents of the interview are substantially as set forth in the Examiner Interview Summary dated November 12, 2008, and as summarized herein.

The Invention

As discussed at the personal interview, in accordance with the present invention, it has been discovered that Alanine-Cpn10 (as disclosed for the first time in the present application) provides a distinct functional advantage over other Cpn10 mutants and fragments previously known in the prior art. For example, the Examiner's attention is directed to the Somodevilla-Torres *et al.* publication (cited in section 9 bridging pages 4-5 of the Office Action). As discussed at the personal interview, this reference reports the results of contract research conducted by the authors on behalf of the current Applicants.

As discussed in greater detail in Applicants' response dated July 15, 2008, the Somodevilla-Torres *et al.* reference is fully consistent with Applicants' assertion that Alanine-Cpn10 provides a distinct functional advantage over other existing Cpn10s. Support for Applicants' assertions regarding "functional advantage" of Alanine-Cpn10 is found throughout the Somodevilla-Torres et al. reference; see, for example:

(i) page 285, column 1, paragraph 1, lines 15 – 19: acetylation or appropriate equivalent thereof, such as an N-terminal addition of alanine, is an important contributor to the immunomodulatory activity of Cpn10; and

(ii) page 285, column 2, paragraph 3, lines 44 to 48: "the modified *E. coli* product, rAla-101 [Alanine-Cpn10] which has immunosuppressive activity *in vivo* of

potency similar to that of the eukaryotic product, fulfills all other objectives and is the molecule of choice for future investigation" (emphasis added).

Inventorship

In view of recently submitted amendments to the claims, inventorship of the present application has been re-evaluated and it has been determined that Halle Morton and Alice Christina Cavanaugh should have been included as inventors herein, based on their role in identifying the claimed polypeptide and uses therefor. Accordingly, documentation is provided herewith to update the inventorship herein, i.e., Request to Correct Inventorship Under 37 CFR § 1.48(c), statements in support of the Request, a replacement Oath and Declaration signed by all inventors of the claimed subject matter, and a Consent of Assignee.

Amendments

In addition, by the present communication, claims 24 and 30 have been amended to define Applicant's invention with greater particularity. No new matter is introduced by the subject amendments as the amended claim language is fully supported by the specification and original claims. In addition, claims 29 and 31 have been cancelled without prejudice, subject to Applicants' right to pursue the subject matter thereof in one or more subsequent filings which claim priority from the present application. Upon entry of the amendments submitted herewith, claims 24-28 and 30 will remain pending. A detailed listing of all claims that are, or were, in the application, irrespective of whether the claim(s) remain under examination, is presented in the Listing of Claims, beginning on page 2 of this communication, with an appropriate status identifier for each claim.

Rejection under 35 U.S.C. § 112, first paragraph (written description)

The prior rejection of claims 1-7, 9-16, 18-20 and 22-28 under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement, is once again

respectfully traversed. As a preliminary matter, this rejection has been rendered moot as to claims 1-7, 9-16, 18-20, 22 and 23 by the cancellation thereof.

It is respectfully submitted that this rejection is not applicable to claims 24-28 for at least the following reasons. Applicants' invention, as defined, for example, by claim 24, requires a pharmaceutical composition comprising:

a pharmaceutically-effective amount of cpn10 comprising a defined amino acid sequence (i.e., a polypeptide comprising the amino acid sequence set forth in FIG. 1 (SEQ ID NO:1)), and

a pharmaceutically-acceptable carrier, excipient or diluent.

There is respectfully submitted to be substantial written description for the compositions embraced by the present claims. See, for example, Figure 1 of priority document Australian Provisional Patent Application No. 2002952492, as well as page 8, lines 14-17, and page 10, lines 8-10 thereof.

Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. §112, first paragraph, are respectfully requested.

Foreign Priority

As discussed at the personal interview, it is respectfully submitted that the priority document fully supports the present invention, as claimed herein. See, for example, Figure 1 of priority document Australian Provisional Patent Application No. 2002952492, as well as page 8, lines 14-17, and page 10, lines 8-10 thereof. Accordingly, acknowledgement of Applicants' entitlement to the claimed priority date of 6 November 2002 is respectfully requested.

Rejections under 35 U.S.C. § 102

. . . under 102(b) over Coates

The rejection of claims 20, 22-26 and 28 under 35 U.S.C. §102(b), as allegedly being anticipated by Coates et al. (WO 02/40038) is once again respectfully traversed.

As a preliminary matter, this rejection has been rendered moot as to claims 20, 22 and 23 by the cancellation thereof. As to the remaining claims (i.e., claims 24-26 and 28), it is respectfully submitted that Coates et al. is not properly applied against these claims.

Applicants' invention, as defined, for example, by claim 24, distinguishes over Coates et al. by requiring a pharmaceutical composition comprising:

a pharmaceutically-effective amount of cpn10 comprising a defined amino acid sequence (i.e., a polypeptide comprising the amino acid sequence set forth in FIG. 1 (SEQ ID NO:1)), and

a pharmaceutically-acceptable carrier, excipient or diluent.

Coates et al. do not disclose such compositions. Instead, as discussed at the personal interview, the Coates et al. reference is directed to compositions containing *Mycobacterium* Cpn10. Alanine-Cpn10 (a recombinant Cpn10 mutant derived from human Cpn10) is clearly distinct from *Mycobacterium* Cpn10. For example, the degree of homology and isoelectric focusing differ substantially for these materials. Thus, *Mycobacterium* Cpn10 only has 37% identity (and 63% similarity) with respect to human Cpn10. Moreover, isoelectric focusing (i.e. pI) of mammalian Cpn10 is substantially different than isoelectric focusing of non-mammalian Cpn10 (e.g. *M. tuberculosis* Cpn10).

Accordingly, reconsideration and withdrawal of this rejection under 35 U.S.C. §102(b) are respectfully requested.

. . . under 102(b) over Morton

The rejection of claims 16, 18-20 and 22-24 under 35 U.S.C. §102(b), as allegedly being anticipated by Morton et al. (US Patent No. 6,117,421) is once again respectfully traversed.

As a preliminary matter, this rejection has been rendered moot as to claims 16, 18-20, 22 and 23 by the cancellation thereof. As to claim 24, Applicants' invention distinguishes over Morton et al. by requiring a pharmaceutical composition comprising:

a pharmaceutically-effective amount of cpn10 comprising a defined amino acid sequence (i.e., a polypeptide comprising the amino acid sequence set forth in FIG. 1 (SEQ ID NO:1)), and

a pharmaceutically-acceptable carrier, excipient or diluent.

Morton et al. do not disclose such compositions. Instead, as discussed at the personal interview, the Morton et al. reference is directed to compositions containing mammalian Cpn10, which does not embrace the specific modified form thereof contemplated herein, i.e., Alanine-Cpn10 (a recombinant Cpn10 mutant derived from human Cpn10).

Accordingly, reconsideration and withdrawal of this rejection under 35 U.S.C. §102(b) are respectfully requested.

. . . under 102(a) over Somodevilla-Torres

The rejection of claims 16, 18, 20, 22, 24 and 29 under 35 U.S.C. §102(a), as allegedly being anticipated by Somodevilla-Torres et al. (Protein Expression and Purification 32:276-287 (2003)) is once again respectfully traversed.

As a preliminary matter, this rejection has been rendered moot as to claims 16, 18, 20, 22 and 29 by the cancellation thereof. As to claim 24, the Somodevilla-Torres et al. reference is not properly applied against this claim in view of the discussion above establishing Applicants' right

to claim priority back to the filing date of priority document Australian Provisional Patent Application No. 2002952492.

Accordingly, reconsideration and withdrawal of this rejection under 35 U.S.C. §102(a) are respectfully requested.

Rejections under 35 U.S.C. § 103(a)

. . . under 103(a) over Morton in view of Kimura

The rejection of claims 1-7, 9-16, 18-20 and 22-28 under 35 U.S.C. §103(a), as allegedly being unpatentable over Morton et al., in view of Kimura et al. (J of International Medical Research 29:214-221 (2001) is once again respectfully traversed.

As a preliminary matter, this rejection has been rendered moot as to claims 1-7, 9-16, 18-20, 22 and 23 by the cancellation thereof. As to claim 24 (and claims dependent thereon), as discussed at the personal interview, and as noted above, Morton et al. does not anticipate the present claims. Further reliance on Kimura et al. is unable to cure the deficiencies of Morton. Similar to Morton et al., the Kimura et al. reference does not disclose pharmaceutical compositions comprising the defined cpn10 mutant required by the present claims.

Accordingly, reconsideration and withdrawal of this rejection under 35 U.S.C. §103(a) are respectfully requested.

. . . under 103(a) over Morton + Kimura +Somodevilla-Torres

The rejection of claims 8 and 29 under 35 U.S.C. §103(a), as allegedly being unpatentable over Morton in view of Kimura, as applied to claims 1-7, 9-16, 18-20 and 22-28 above, and further in view of Somodevilla-Torres et al. is once again respectfully traversed, and has been rendered moot by the cancellation of each of the rejected claims.

Accordingly, reconsideration and withdrawal of this rejection under 35 U.S.C. §103(a), as are respectfully requested.

Conclusion

In view of the above amendments and remarks, Applicant respectfully requests reconsideration and favorable action on all claims. In the event any matters remain to be resolved in view of this communication, the Examiner is encouraged to contact the undersigned so that a prompt disposition of this application can be achieved.

Respectfully submitted,

Date 12/18/08

By _____

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Enclosures: Request to Correct Inventorship
Statements in support of Request
Replacement Oath and Declaration
Consent of Assignee